CHEMICAL & ENGINEERING NEWS

C&EN

APRIL 25, 1994

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ANTICANCER STRATEGY FOCUSES ON TELOMERASE ENZYME PAGE 42

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ISO 9000

Chemical industry takes active role in developing international management standards

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CHEMICAL & ENGINEERING NEWS

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NEWS OF THE WEEK

■ Chemists at Boston College develop a molecular "brake," involving a side chain that reversibly slows down a triptycene "wheel." **Page 6**

■ A new semiconductor laser, the quantum cascade laser, which can be tailored to emit light of any frequency in the mid- to far-IR range, has been developed by AT&T Bell Labs scientists. **Page 7**

■ Industrial release of toxics into the U.S. environment fell in 1992 for the fifth straight year, but waste generation rose slightly. **Page 8**

■ Sales of Monsanto's bovine growth hormone are booming, despite attacks on its use from lawmakers and consumer and environmental activists. **Page 8**

■ Top executives from seven tobacco firms reject charges of nicotine manipulation and research suppression at a House hearing. **Page 9**

■ Danish producer Novo Nordisk opens what may be the largest multipurpose enzyme plant in North America. **Page 9**

COVER: Photo by Uniphoto Picture Agency

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BUSINESS

Cytec Industries' chairman Darryl Fry strives to create "cultural discontinuity" in the newly independent chemicals company and to establish the firm in the commodity and specialty sectors. **Page 29**

GOVERNMENT

Predicted effects of fixed or shrinking research budgets on federal labs, universities, and researchers are now realities, dictating that changes be made in how science is done. **Page 35**

Current U.S. global-change research program will not provide decisionmakers with the information needed to respond to global change, say speakers at a symposium. **Page 39**

SCIENCE/TECHNOLOGY

Canadian researchers report finding the enzyme telomerase in cancer cells but not in healthy cells, suggesting that its inhibitors could be effective anticancer drugs. **Page 42**

Construction has begun on a new laboratory at Hanford and on a 1,000-MHz NMR system that will be a centerpiece in the facility, which will focus on environmental restoration. **Page 44**

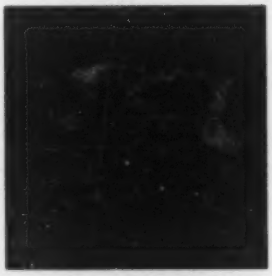
EDUCATION

NOBCChE, an organization for black chemists and chemical engineers, is changing—expanding its membership base, adding to its student chapters, and broadening its activities. **Page 47**

MEETINGS

Program of the 49th ACS Northwest Regional Meeting includes more than 150 invited and contributed papers in 14 symposia and workshops ■ Graduate Research Polymer Conference to be held in June at Penn State University will provide a forum for graduate students. ■ National Chemical Information Symposium to be held in Vermont in June will feature interactive sessions. **Page 49**

NEWS FOCUS



Chemical companies are seeing beneficial results from ISO 9000 registration as the international standards become a basic component of quality management and evolve rapidly in the environmental arena. Page 10

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LETTERS

CHEMICAL SAFETY

Potential hazard in hydrosilylation of D_4^{Vi} with D_4^{H}

We would like to comment on a recent communication by M. J. Michalczyk, W. E. Farneth, and A. J. Vega in *Chemistry of Materials* [**5**, 1687 (1993)]. In this paper, one of us describes a synthesis of highly cross-linked carbosiloxane glasses by hydrosilylation of $[(Me(Vi)SiO)_4]$ (D_4^{Vi}) and $[(Me(H)SiO)_4]$ (D_4^{H}) according to the procedure described in the General Electric patents by H. F. Lamoreaux. In all preparations of these glasses at DuPont, no safety problems or unusual hazards were observed in carrying out the hydrosilylation reaction D_4^{Vi} with D_4^{H}.

However, recent communication between us has brought to our attention some potential safety hazards associated with this synthesis. In particular, researchers at General Electric have sometimes observed uncontrollable exotherms or explosions during the hydrosilylation of D_4^{Vi} with D_4^{H}. Exothermic reactions were also observed when an excess of D_4^{H} was used. At DuPont, we have observed similar exotherms during the hydrosilylation of tetravinylsilane with D_4^{H}. Because of the potential safety problem associated with this and other related syntheses, we now suggest caution be used when carrying out the hydrosilylation reaction of D_4^{Vi} with D_4^{H} and recommend that hydrosilylations using monomers with low flash points be carried out behind a safety shield at the smallest possible scale with a low level (below 20 ppm) of platinum. The typical commercial product lines that employ platinum cures have no hazards.

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Phase-transfer catalysis

I read with interest the meeting brief (C&EN, March 28, page 43) that reports phase-transfer catalyzed reactions in supercritical fluids and suggests that this is the first work of the sort to have been performed. It is worth noting that phase-transfer catalyzed reactions have been previously carried out in environmental analytical chemistry applications. Phase-transfer catalysts have been used with supercritical fluid extraction (SFE) to simultaneously derivatize and extract organic chemicals from environmental matrices.

Two reports document the derivatization of chlorophenoxy acid herbicides by phase-transfer reactions under in-situ SFE conditions. Last year, Viorica Lopez-Avila and coworkers formed the pentafluorobenzyl derivatives of several chlorophenoxy acid herbicides using pentafluorobenzyl bromide and triethylamine as the catalyst [*J. Agric. Food Chem.*, **41**, 2039 (1993)]. Earlier this year, Richard J. Wells of the Australian Government Analytical Laboratories reported to the 5th International Symposium on Supercritical Fluid Chromatography & Extraction on the use of tetrahexylammonium hydroxide with methyl iodide for the in-situ derivatization of 2,4-D from water immobilized on a solid support. Quaternary ammonium ion pair reagents were used initially in SFE, in the absence of an additional electrophilic alkylation reagent, for the extraction and derivatization of microbial phospholipid fatty acids from whole cells of *Escherichia coli*, chlorophenoxy acid herbicides from soils and sediments, and aliphatic and aromatic sulfonated surfactants from sewage sludges (Steven B. Hawthorne, et al. [*Anal. Chem.*, **64**, 405 (1992)] and Jennifer A. Field, et al. [*Anal. Chem.*, **64**, 3161 (1992)]). Clearly, quaternary ammonium ion pair reagents and other phase-transfer catalysts show tremendous potential for application in chemical engineering and environmental chemistry.

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Chemical Companies See Beneficial Results From ISO 9000 Registration

International standards have become a basic component of quality management and are evolving rapidly in the environmental arena

Ann M. Thayer
C&EN Northeast News Bureau

ISO 9000 standards have taken force worldwide. Although ISO 9000 standards are just five among the thousands of standards issued by the 48-year-old International Organization for Standardization (ISO), their impact cannot be ignored. This year, updated and slightly modified ISO 9000 standards are expected to be published. By the end of the decade, more significant changes—to broaden concepts and update the standards relative to marketplace and technology needs—are anticipated.

Although there will be some effect from these changes, even bigger events are in the making. In June 1993, ISO created Technical Committee 207 (TC 207) to begin work on new standards for environmental management systems (EMS). The standards' ramifications worldwide, and to the chemical industry, which has become heavily involved in their development, will be great. TC 207's activities are being scrutinized closely and will continue to be into 1995 when the first environmental standards are expected to be published.

Companies with ISO 9000 guidelines already in place probably can expect to see similarities in the new standards for EMS. The ISO 9000 series, first published by the Geneva-based ISO in 1987, consists of five generic standards, which provide only guidance—and not prescriptive performance limits—for companies in establishing quality management systems. Key to the process is not just the setting up of a system, but also the thorough documentation of a company's operations.

Once thought to be of primary importance for access to the European market, ISO 9000 standards also are serving as a baseline process through which companies respond to customers and document internal quality programs. More than 70 countries have adopted the ISO 9000 series for use as national standards; thousands of organizations, including government agencies, are using the voluntary standards. In the U.S. and Canada, the number of ISO 9000 registrations reached about 3,600 in the first quarter of 1994, a jump from about 1,500 a year ago and from about 400 two years ago, according to CEEM Information Services, Fairfax, Va.

The chemical industry leads all other industries in the U.S. in gaining ISO 9000 certification, according to CEEM, with chemical companies now accounting for more than 600 registrations or about 19% of total U.S. registrations. The most common registrations in the chemical industry are to ISO 9002, which covers quality systems and assurance in manufacturing and in the delivery of a product, but does not cover design. In a C&EN survey of 38 companies, including 36 major chemical producers and two engineering firms, companies gave their views on the impact of ISO 9000 standards on company operations.

It was only a few years ago that most U.S. chemical companies began registering their operations to one of the ISO 9000 standards. Having taken root largely in Europe, ISO 9000 standards registration often was first sought by overseas operations of U.S. companies or by foreign companies. Now, many U.S. companies have had a few years of experience with one or more of the periodic six-month reassessments since initial registration.

Registration by a third-party organization, generally called a registrar, means that a company's quality management and quality assurance systems have been audited against the written standards. Registration is conferred only after a successful on-site audit by a team of auditors and recognizes that a company has in place a fully documented system that it consistently follows. Subsequently, chemical companies say that they have started to see tangible results, such as improved efficiency and cost savings, from being ISO 9000 registered.

ISO 9000 is not a product certification standard; registration in no way measures or recognizes the quality—good or bad—of a company's final product nor does it mean that two companies with ISO 9000 registrations are equivalent. To presume otherwise is probably the greatest misconception, and perhaps misuse, of ISO 9000 standards. However, ISO 9000 may play a role in product liability and other legal matters through the technical documentation it creates.

Separate registrations can apply to individual company sites, divisions, facilities, operations, or production processes, or a single registration may cover multiple functions, sites, or even an entire company. Not counting DuPont's more than 200 registrations, which tend to be along product lines, the 38 companies surveyed by C&EN accounted for registrations covering more than 780 sites or business operations. About half of the companies had operations registered to ISO 9002 alone and another third had sites registered to ISO 9001, which covers design, and 9002. Two engineering firms had ISO 9001 registrations alone.

Companies seek ISO 9000 registrations for a few major reasons. Of the 38 surveyed companies, 24 cite internal quality management and continuous improvement initiatives as a reason for implementing ISO 9000 standards. But competition and market pressures, initially in Europe and now more frequently in the U.S., were mentioned by 23

companies. The third most important motivating factor, mentioned by 17 companies, is customer concerns, requests, satisfaction, or recognition.

These results correspond well with a July 1993 survey conducted jointly by the accounting firm Deliotte & Touche, located in Atlanta, and Quality Systems Update, a CEEM publication. Among the 110 chemical companies included in the 620-company survey, customer expectations and demands were ranked as the leading reason for registration by 26% of the companies and quality benefits by 23%. Contrary to once widely held beliefs as to why companies seek registration, marketing and competitive concerns ranked much lower, especially in Europe.

Historically, the drive for registration began in Europe because companies were worried that if they weren't registered, they would have difficulty doing business there, says Paul Z. Larson, vice president of operations for DuPont specialty chemicals. "As the company proceeded, it found that there were a lot of internal benefits to ISO 9000 registration." By the time its efforts are completed, DuPont expects to have more than 330 worldwide registrations. Most of its current registrations are in North America and Europe, although the company also has registered sites in Asia and Latin America.

Registration takes time, money

The cost, effort, and time companies say is required to achieve ISO 9000 registration suggest that it is not a process to be undertaken lightly. Depending to what level a company's operations already are documented, the process toward registration may move ahead more or less quickly. Based on information from 31 of the 38 companies surveyed by C&EN, chemical companies estimate that the average time to obtain registration is about 20 months. The shortest time needed was six months; the longest times were upward of several years, but the latter often represent "man-years."

Estimates of the amounts of time and money invested vary depending on whether companies are working on multiple-site registrations, on the size of operations being prepared for registration, and on the accounting system for employee hours devoted to the project. The average cost, including both external costs for consultants and registration audits and internal preparation costs, was $316,000 per site based on information from 13 companies in C&EN's survey, as compared with $348,000 from Deliotte & Touche's survey.

Many companies do not count the internal costs of preparation, documentation, and training under a quality system. Instead, when existing employees are used in the process, the costs often are considered part of normal personnel expenses for employee activities related to necessary business functions. The costs for third-party audits ranged from about $10,000 to $30,000 per site according to 11 companies in C&EN's survey. Deliotte & Touche found the average external costs—including registrars and consultants, which are used by about half of the companies—to be $51,000.

Some chemical company quality or ISO 9000 managers estimate that costs can be recovered within six months to several years. Others in the industry believe that cost savings will be minimal. However, the vast majority—while expecting some positive return in the long term—say they cannot or have not quantified or documented any cost savings. Based on company figures from the Deliotte & Touche survey, average annual savings of $224,000 were calculated. In addition, costs and potential cost savings were found to scale directly with company size in terms of sales.

Long-term benefits

Whether the payback is concrete or intangible, those who believe there is one say that it is a direct and nearly immediate result of improved production processes, increased ef-

FMC uses advanced manufacturing techniques and quality assurance procedures to produce high-purity lithium metal ingot that meets the stringent demands of battery manufacturers.

ficiency and productivity, and decreased errors or nonconforming products as a result of corrective and preventive action. Companies in the Deliotte & Touche survey listed improved documentation (32%), greater quality awareness (26%), positive cultural changes (15%), and increased productivity and efficiency (9%) among the internal benefits.

"It helps simplify our processes, it drives us to look in detail at the many things we do every day and [to] examine the value of each step and eliminate those where we aren't adding value and add where we need some support," says Larson of DuPont. The results were a higher level of operating discipline, a better quality product, and a more economical way of supporting efforts at its plants. "[ISO 9000 also has made] it easier to move people around our plants as we've downsized," he says, "[by having] procedures that are very carefully developed, which helps in training efforts."

Many managers frequently express the axiom that ISO 9000 standards cause a company to "document what it does and do what it documents." The benefits are so significant, stresses Joan M. Desiderio, director of total quality at Lonza, Fair Lawn, N.J., that "if you are not going to use ISO 9000 for the internal benefits, you shouldn't even bother doing it." Since Lonza went through its preparation for complying with the standard at least two major internal benefits have been realized. One is having exactly documented company operations, outside actual manufacturing processes, for the first time. A second major benefit is that the process was a "tremendous educational experience and creator of teamwork," allowing employees to better understand the overall work process and their roles in it.

"I don't believe Lonza was unusual. I believe that most companies don't have a lot written down for their business processes, although they do for manufacturing," she says. "Yet there is so much talk about companies doing [corporate] reengineering, but they have no idea what is currently happening [in their company]. I don't understand how one can reengineer something when it isn't even known what that something is." Lonza has eight ISO 9002 registrations covering the company's headquarters, which has functions such as purchasing and customer service serving its plant sites, and seven plants.

Desiderio strongly believes that the key to the ISO 9000 registration process is having the employees who actually do the work create the documentation for what they really do. "Only if Lonza needed to fill a gap to comply with the standards did we want to change any [procedures]," she adds.

Not surprisingly, Lonza very definitely decided against using external consultants. Its employee involvement and documentation process have served the company well when it encounters a problem, explains Desiderio, because problems can be addressed very quickly and very consistently. Employees can see whether things were not done in accordance with the system and should have been or, if done according to the system, how the system should be changed to correct the problem.

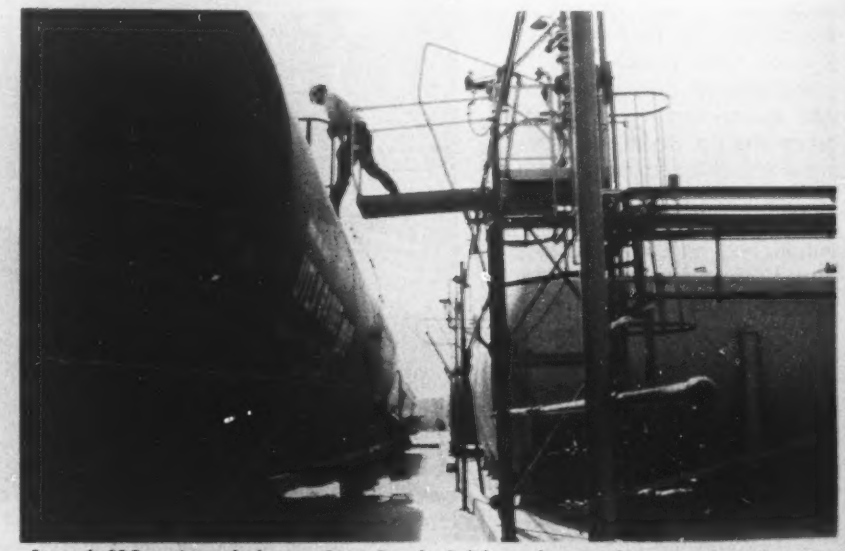
"The next step, which we are doing now, is to take the documentation and look at how we can improve it, how we can streamline it, how we can get rid of the non-value-added elements and find where we have built in some error that can be eliminated," she says. "And now we are starting with something concrete instead of just everyone's guesswork, so from that point of view we've built a lot of discipline and consistency."

External benefits also are expected from ISO 9000 registration. Of the chemical companies in the Deliotte & Touche survey, higher perceived quality was ranked first by 34%, increased customer satisfaction by 27%, and having a competitive edge by 22%. Since much of the impetus behind ISO 9000 registration is to meet customer quality assurance requirements, one often anticipated savings is a reduced number of audits by customers who recognize registration as a commitment to certain quality practices.

However, the survey found that only 9% of chemical companies cited reduced audits as an external benefit. Nonetheless, many companies do report that customer audits, even if they are not reduced in number, are shorter or that they focus on product performance or environmental, health, and safety issues not already addressed by the standards. And the converse also is expected to become increasingly more common as companies, having focused for some time on getting internal efforts in place, start to look outward and request ISO 9000 registration of suppliers or those who wish to be preferred suppliers.

Registrar choice important

ISO 9000 registration carries weight only if it is recognized. Thus, the choice of an outside registrar often is dictated by customer acceptance. Although different registrars are used by different chemical companies, which individually also may use more than one registrar for different company sites, several registrars have amassed a great deal of



Lonza's ISO-registered plant at Long Beach, Calif., produces and transports surfactant.

Many countries worldwide have adopted ISO 9000 series as a national standard

In January 1994, the 74 countries that had adopted ISO 9000 series were Algeria, Argentina, Armenia, Australia, Austria, Azerbaijan, Barbados, Belarus, Belgium, Brazil, Bulgaria, Canada, Chile, China, Colombia, Cuba, Cyprus, Czech Republic, Denmark (but not Greenland), Egypt, Finland, France, Germany, Greece, Hungary, Iceland, India, Indonesia, Ireland, Israel, Italy, Jamaica, Japan, Kazakhstan, Kyrgyzstan, Malaysia, Mexico, Moldova, Netherlands, New Guinea, New Zealand, Norway, Pakistan, Philippines, Poland, Portugal, Romania, Russia, Singapore, Slovakia, Slovenia, South Africa, South Korea, Spain, Sri Lanka, Sweden, Switzerland, Taiwan, Tajikistan, Tanzania, Thailand, Trinidad/Tobago, Tunisia, Turkey, Turkmenistan, U. K., Ukraine, Uruguay, Uzbekistan, U.S., Venezuela, Yugoslavia, Zambia, and Zimbabwe. The standards have also been adopted by the European Union.

Source: CEEM Information Services

experience in the chemical industry. According to CEEM, 10 registrars account for about 91% of U.S. chemical company certifications, and each lists chemical industry certifications as between 15 and 50% of their business.

Leading the group is Quality Systems Registrars, Herndon, Va., with just more than 100 registrations, followed closely at 96 by the joint registration activity of Underwriters Laboratories, Melville, N.Y., and British Standards Institution (BSI), located in the U.S. in Tysons Corner, Va. BSI, in addition to being part of the British organization involved in standards writing, serves as a registrar and accounts for nearly 80 registrations in the U.S. chemical industry.

Quality Management Institute, in Canada, and Det Norske Veritas Industry Americas, the Houston-based arm of the Norwegian DNV, each has about 50 registrations in the industry. Companies with just more than 30 chemical company registrations each are ABS Quality Evaluations, Houston; Bureau Veritas Quality International, Jamestown, N.Y.; Lloyd's Register Quality Assurance, Hoboken, N.J.; SGS International Certification Services (formerly SGS Yarsley), Hoboken; and Underwriters Laboratories.

In addition to knowledge about a particular industry sector, registrars generally are chosen by chemical companies on the basis of other factors such as their reputations, capabilities, experience, and location. Many choices are dictated by concerns about a registrar's own accreditation standing and the training and certification of a registrar's auditors. Companies also may look for registrars that have dual accreditation from, or a mutual recognition agreement between, the two countries in which its plant sites to be registered are located.

Having spoken with and screened many potential registrars, Lonza's Desiderio says the choice of registrar was dictated not only by accreditation, knowledge, costs, and location, but also by the registrar's philosophy. "What I liked about [the registrar chosen] was that they clearly understood that Lonza is in the business of manufacturing and selling chemicals," she says, "and that we are not in the business of designing quality systems.

"Many of the registrar companies I talked to gave me the impression that, in their view, Lonza's reason for being should be to have a great quality system and that the company only manufactures chemicals on the side. The registrar [chosen had] a certain business common sense, but with the integrity that Lonza still had a standard to meet."

What has not yet been formalized is an international accreditation system for the recognition of registrars or for the certifications of individual auditors. On a national level,

many different institutions exist to recognize these organizations. In Europe, many accreditation groups are governmental or quasi-governmental bodies. Two more established ones are the Dutch Council for Certification (RvC) and the National Accreditation Council for Certification Bodies (NACCB) in the U.K. However, only RvC certifies registrars outside of its own country.

In the U.S., the Registrar Accreditation Board (RAB) was formed in 1989 as an American Society for Quality Control (ASQC) affiliate. RAB, which has accredited 15 third-party registrar organizations, has joined with the American National Standards Institute (ANSI) in the accreditation process. ANSI represents the U.S. as a member of ISO. RAB, ASQC, and the U.K.-based Institute for Quality Assurance (IQA) also have developed programs for the training and certification of individual auditors.

In March, RAB, IQA, and the Quality Society of Australasia in Australia and New Zealand signed a mutual recognition agreement. Although there are not as many auditor certification organizations as there are registrar accreditation bodies, says George Q. Lofgren, president of RAB, the need for harmonization is evident in certification too. The agreement states that, while working toward a uniform system of requirements for certifying auditors, these three organizations have enough experience with and enough confidence in each other's current programs to recognize the others' certifications.

Organizations accrediting registrar firms tend to follow criteria set up by ISO and the other major international standards organization, the International Electrotechnical Commission (IEC). A set of similar standards, under the European Norm (EN) 45000 series, also are used. EN standards are issued by the standards-making organizations for the European Union (EU)—the European Committee for Standardization (CEN) and the European Committee for Electrotechnical Standardization (CENELEC).

In response to the EU's preference for government-related recognition systems, the Department of Commerce, acting through the National Institute of Standards & Technology (NIST), has proposed the National Voluntary Conformity Assessment System Evaluation (NVCASE) program. This program will provide a basis, with other federal agency programs, for the U.S. government to assure other governments that U.S. assessment bodies are competent to provide results acceptable for regulatory purposes. ISO 9000 is expected to be one requirement under the evolving European system for conformity assessment and regulated products.

The NVCASE program will apply not only to ISO 9000 registrars, but also to organizations doing product testing and certification, such as ANSI. A proposed rule was published in July 1993, and NIST has since incorporated public comments into a final document now in the review process. In its current form, the NVCASE program is expected to be able to recognize accreditation organizations and would be involved directly in accrediting registrars only when acceptable alternative programs do not already exist.

Numerous other groups have been formed to look into the issues surrounding registrar recognition and to share information. In early 1993, the International Accreditation Forum (IAF) was created to increase cooperation among international accreditation bodies toward establishing mutual recognition agreements. "We need to harmonize our activities if there ever is to be true international recognition of the registrations that are issued," says Lofgren. He describes IAF as a "user's group" where common concerns as well as differences in work practices and in the ways organizations interpret standards can be discussed.

Similarly, the Independent Association of Accredited Registrars (IAAR) was formed in the U.S in 1993. The group of accredited registrars is attempting to promote consistency among registrars and ensure integrity of the registration process. In addition to trying to reach a nonbinding consensus on an interpretation of the ISO 9000 standards, IAAR is addressing how organizations that offer both consulting and registration services can avoid conflicts of interest.

"The main thing is to make sure that this whole process has merit," says Yehuda Dror, general manager of quality rating and certification at DNV. "Because if the registration process is not perceived as having value, then it's just another paper exercise." And, while admitting a certain level of self-interest, Dror adds, "From what we have seen and what industry tells us, compliance with the standard as manifested by a registration has real value."

Internationally, ISO and IEC have established the Quality System Assessment Recognition (QSAR) committee to make recommendations on a system for the worldwide recognition of registrars. Lofgren, a QSAR member, says the group has produced an initial draft document that has gone through a comment period by ISO and IEC members (the national standards organizations). QSAR met this month to consider these comments before its recommendations are forwarded to ISO and IEC for their September meetings.

QSAR initially came to the conclusion, says Lofgren, that international recognition at the registrar level would

Lonza's esters and surfactants production plant at Williamsport, Pa., has successfully competed the ISO certification process.

ISO 9000 standards cover quality management systems

The International Organization for Standardization (ISO), based in Geneva, issued the ISO 9000 series of voluntary standards for quality management systems in 1987. Updated versions of the standards will be issued in final form this year.

The five generic standards provide guidance in setting up quality management systems. These standards apply to the elements and practice—primarily through documentation—of such systems, but not to the specific form or means for implementation. Nor do the standards set any technical or performance requirements. Third-party certification against the standards indicates that a company has a documented quality management system in place and follows it consistently. The five standards are:

- ISO 9000. Entitled "Quality Management and Quality Assurance Standards: Guidelines for Selection and Use," it is a guidance standard, setting forth principal concepts and defining terms. It also introduces the other four standards and provides guidance on the selection and use of ISO 9001, 9002, and 9003 standards.
- ISO 9001. Provides a model for quality assurance in the design, development, production, installation, and servicing of products or services. The most comprehensive of all the standards, it includes all of the requirements found in ISO 9002 and ISO 9003.
- ISO 9002. Provides a model for quality assurance in production, installation, and servicing. In the revised standard, ISO 9002 includes servicing but, unlike ISO 9001, it does not include design elements.
- ISO 9003. The least comprehensive standard, it provides a model for quality assurance when only final inspection and testing are required.
- ISO 9004. In contrast to the other standards, this one offers guidelines for developing and applying internal quality management elements and activities. It also looks in more detail at elements contained in ISO 9001, 9002, and 9003.

Originally designed to be used in two-party purchaser-supplier contracts, the ISO 9000 series of standards is being applied broadly through third-party certification of a company's quality system operations. In practice, the most important standards are ISO 9001, 9002, and 9003, which require some, but not all, of the same 20 elements as listed in CEEM Information Services' ISO 9000 Handbook, 2nd Edition.

System element	ISO standard		
	9001	9002	9003
Management responsibility	●	●	●
Quality system	●	●	●
Contract review	●	●	●
Design control	●	●	●
Document and control data	●	●	●
Purchasing	●	●	●
Control of customer-supplied product	●	●	●
Product identification and traceability	●	●	●
Process control	●	●	●
Inspection and testing	●	●	●
Control of inspection, measuring, and test equipment	●	●	●
Inspection and test status	●	●	●
Control of nonconforming product	●	●	●
Corrective and preventive action	●	●	●
Handling, storage, packaging, preservation, and delivery	●	●	●
Control of quality records	●	●	●
Internal quality audits	●	●	●
Training	●	●	●
Servicing	●	●	●
Statistical techniques	●	●	●

● = Comprehensive requirement.
● = Less comprehensive requirement than in ISO 9001 and 9002.
● = Not present.

become unworkable because of the growing numbers of registrars. However, there has been strong support from some quarters for a system that includes peer recognition of registrars. QSAR's initial recommendations instead were aimed one level up—at the bodies which accredit registrars.

"What was envisioned is that there will be some system of peer evaluation and mutual recognition among the accreditation bodies," he says. "When that exists . . . all of the registrars that have been accredited by a recognized accreditation body will be able to issue a certificate that perhaps has a unique ISO-IEC mark on it. And that mark will be the mechanism through which eventual, universal recognition will be achieved." Whatever form the international system takes, many people anticipate that there will be an acceptance period, not only by countries, accreditation bodies, and registrars, but also by clients and customers, that will be critical to the process's ultimate success.

Barriers and criticisms

Many people hope that ISO 9000, as an international standard, will establish consistent international practices and terminology for quality management. But the international recognition issues for registrar accreditation and auditor certification will take time to be resolved. And implementation of the standards faces criticisms and barriers.

In the Deliotte & Touche survey, 24% of the chemical companies indicated that document development was a main barrier to registration. Another 16% said that developing procedures was a significant barrier. These two activities also were listed as the most time consuming.

Company managers with experience in ISO 9000 registration admit that these can be problems, especially if a company is not careful in how it creates its documentation. The standards are generic and offer no specific direction for certain industry sectors or operations within sectors. To address this problem, industry trade associations—for example, the Chemical Manufacturers Association (CMA), the Synthetic Organic Chemical Manufacturers Association, and the Society of the Plastics Industry—and organizations such as ASQC have formed industry focus groups to offer workshops, training, and guidance in intrepeting the standards and applying them to specific activities.

One frequently mentioned criticism of the ISO 9000 standards is that they are overly bureaucratic, requiring excessive documentation. "ISO only indicates where you should have documentation, not how much you have to write,"

explains Dror of DNV, and the key is determining how much is enough. A related criticism is that the system becomes too unwieldy for practical application and doesn't represent what companies really need to have in place. But as experience with ISO 9000 implementation has increased, company managers say, so too has the ability to avoid potential pitfalls.

"The overall directive Lonza put in place for documentation was that it had to be user friendly," says Desiderio. "It wasn't being written to be put on a shelf and it wasn't designed to satisfy auditors ... and the company made it clear to [the auditors] that it was written for Lonza's employees and to reflect how the company runs its business." Lonza's procedures, which can be referred to by any employee through a companywide computer system, are flow charts rather than "detailed verbiage," she adds, and list only critical activities that must take place and who has responsibility. When needed, more detailed work instructions are documented.

Many chemical company managers surveyed by C&EN say that ISO 9000 is only one element of their larger total quality management system. Creators of the ISO 9001 through 9003 standards themselves state: "The requirements in these external quality assurance standards are viewed as minimum good business practices for a supplier company in any industry/economic sector." ISO 9000 standards, by providing basic directives for documentation and training, are considered an important foundation for use with other, broader, management programs.

Companies that use ISO 9000 registration as a trophy or a blue ribbon are met with suspicion, if not derision, by quality managers. And customers unfamiliar with the details of ISO 9000 registration may be too naive to know better. While admitting that registration offers a feeling of achievement and the desire to brag because of the effort required, these same company quality managers stress that ISO 9000 registration means only that a company has succeeded in putting a basic system in place.

ISO 9000 registration "only implies consistency," says Desiderio. "My next question would be: What's your consistency level? Because a company that is certified to the standard can be consistently mediocre in its products and services." Quality managers, like Desiderio, say it is how a system is used that will determine whether a company becomes a "class quality organization." "It's what a company does using that system and the standards it sets that will then allow it to become consistently better," she adds.

However, a frequent criticism of ISO 9000 standards is that in creating documented procedures the standards are too "static" and do not allow for change or continuous improvement. But again, company quality managers who support ISO 9000 say documentation forces a company to look at its processes and then serves as a framework within which consistent changes and improvements can be made. And changes that are a necessary part of staying competitive can be addressed in the reassessment process and can be achieved without falling out of compliance.

Changes in standards

Revisions to ISO 9000 standards are expected to be published this year, possibly by the summer, as part of an ISO requirement that standards be reviewed every five years. Modifications of the standards are expected to respond to marketplace needs and reflect the practical experience and problems organizations have had in using the standards. Although updating the standards to reflect both marketplace and technology advances, the changes are not expected to alter the form, intent, or continuity of the series but rather to improve their utility. Draft copies of the revised standards have been made public.

"I believe the new standards are written much, much better," says Dror. "They are streamlined ... and there is much less vagueness." In general, the revisions will provide better alignment throughout the series, clearer definitions of terminology and concepts, and an increased emphasis on an organization's customers and stakeholders. The conformance standards—ISO 9001, 9002, and 9003, which were designed to be used in two-party contractual situations—will "officially" recognize third-party registrations for external quality assurance activities. And revised standards are expected to discuss the specific role of documentation in a broader range of areas.

Companies should not misinterpret these requirements necessarily to mean that they must generate more paper, says Dror. "Even though there was no requirement on documented procedures for purchasing in the old standards, I have yet to see any company that doesn't have [purchasing documented]," he states as an example. "I think that ISO took the reality [of what people were doing] and tried to align the system around it." The modified standards also will address one of the most frequently asked questions, he adds: that of whether documentation for a quality management system can be computerized.

Whether the changes have a major or a minor impact on a company's quality system and registration will depend on how an organization previously complied with the standards. "Organizations that looked at the standards and tried to do just the basic minimum to comply probably will have a bit more difficulty than those who did it more with an eye for what works for them," explains Dror. He points

Union Carbide's wire and cable semiconductives compounding facility at the Seadrift, Tex., petrochemical complex is ISO registered.

Board accredits U.S. ISO 9000 registrars

The Registrar Accreditation Board (RAB), based in Milwaukee, is a private-sector organization that accredits organizations to conduct quality system assessments. Established by the nonprofit professional group, the American Society for Quality Control, it has joined with the American National Standards Institute (ANSI) to assure the competence of third-party registrars. Of at least 45 registrars practicing in the U.S. and Canada, including North American arms of many overseas registrars, 11 have applied for accreditation under the ANSI-RAB program. Another 15, currently with RAB accreditation, are awaiting recertification under the joint ANSI-RAB program:

- ABS Quality Evaluations, Houston.
- American Society of Mechanical Engineers, New York City.
- A.G.A. Quality, Cleveland.
- AT&T's Quality Registrar, Union, N.J.
- Bellcore Quality Registration, Piscataway, N.J.
- Bureau Veritas Quality International, Jamestown, N.Y.
- DLS Quality Technology Associates, Camillus, N.Y.
- Intertek Services, Fairfax, Va.
- KPMG Quality Registrar, Montvale, N.J.
- Lloyd's Register Quality Assurance, Hoboken, N.J.
- National Quality Assurance, Boxborough, Mass.
- Quality Systems Registrars, Herndon, Va.
- Steel Related Industries, Wexford, Pa.
- TRA Certification, Elkhart, Ind.
- Tri-Tech Services, Pittsburgh.

out that the accreditation bodies have indicated to registrars that the organizations they audit will have to be in compliance with the revised standards one year from the date of publication.

Registrars are taking different approaches, says Dror, but in general are expected to offer a "grace period" before clients must comply with the revised standards. For example, DNV sent out an advisory note outlining how it plans to make the transition. He explains the procedure: If a company's periodic reassessment audit comes within three months of publication, the company will be assessed against the revised standards but any noncompliance issues will not affect registration. However, by the next six-month audit, or for those whose audit comes after three months, the new standards must be met.

Companies that have not yet had their initial registration audit with DNV, but will have it within three months of publication, can choose to follow either the old or new standards, although DNV recommends following the revised ones, says Dror. Regardless, DNV recommends that companies begin preparation by looking at the draft standards, because the substance is fixed even though editorial changes still may be made. Registrars already are willing to assess companies with respect to the modified standards but, because the modified version is still a draft, cannot yet register them, he adds.

The revisions to come out this year are the first part of a two-phase review strategy by TC 176, the ISO technical committee that developed the ISO 9000 standards. Whereas the original standards were designed with hardware manufacturing in mind, the phase II revisions are expected to further integrate concepts, technology, and terminology among four generic product categories—hardware, software, processed materials, and services. Revised standards also are anticipated to include broader quality management concepts such as continuous improvement, customer satisfaction, and procedures to be used by companies to track product quality performance.

TC 176 hopes the revised generic standards will meet marketplace needs and help avoid the proliferation of industry or other sector-specific standards either supplemental to or derived from the ISO 9000 series. Four strategic goals are set by TC 176 for the ISO 9000 standards—universal acceptance, current compatibility, forward compatibility, and forward flexibility. Phase II revisions are expected before the end of the decade.

Environmental standards

Before the major revisions to ISO 9000 standards are published, new standards for environmental management are expected from ISO. Despite many anticipated similarities to ISO 9000 standards, early expectations are that the environmental standards will, at least initially, be separate ISO 14000 series standards. To ensure continuity among all of the standards and avoid duplication or redefinition of terms or concepts, a coordination group has been formed between TC 176 and TC 207. But many people who follow, or are involved with, standards development expect the next ISO 9000 revisions to include, or at least reference, the environmental standards.

"There are a lot of aspects to the environment that are quite different from quality," says W. Ross Stevens, senior program manager for corporate issues at DuPont and a member of TC 207. "The fundamental difference is that quality is a contractual arrangement between a buyer and a seller, whereas the environment is a much more complex relationship in which a full range of stakeholders must be satisfied."

Growing worldwide environmental concerns have heightened the interest in companies' having EMS, in part to meet regulatory requirements and to report on performance. Many regional and national—voluntary and mandatory—activities are emerging. Because there are many similarities among various emerging standards, there is a desire to "level the playing field" through a single, comprehensive, and generally accepted scheme for environmental concepts and practices.

In the interest of harmonization and facilitating trade, ISO hopes to avoid simultaneous development of regional and international standards. Thus, it is working rapidly to develop international EMS standards, and, if successful by the mid-1995 deadline, have them accepted by CENELEC and CEN for use under the Eco-Management and Auditing Scheme (EMAS) in Europe. "Do it once, do it right, do it internationally" was the motto presented by James L. Dixon, secretary of TC 207 and program manager for the Canadian Standards Association at a joint ANSI, ASQC, and ISO conference last October.

TC 207 held its first meeting in June 1993 and the mo-

ISO 9000 plays important role for chemical producers and engineering firms

A C&EN survey of 36 companies that responded to questions on ranking found that ISO 9000 standards are an element that affects at least 10 different areas of company operations.

The most important impact of ISO 9000 standards is considered to be its enhancement of internal quality management or practices, followed closely by its importance in overseas operations and a company's ability to compete. The areas in which ISO 9000 is considered of less importance are relationships with suppliers and the related area of customer and supplier audits. ISO 9000 standards are deemed to have some positive economic impact, but this did not rank as high in importance as most of the other areas.

When broken out by company type, the overall trend in responses remains. However, diversified and specialty manufacturers rank the importance of ISO 9000 in overseas and domestic operations, as well as the ability to compete, higher than do the manufacturers of basic chemicals. Similarly, ISO 9000's importance in customer and supplier audits ranks lower with basic chemical producers.

Area of company operation	Average response by company type (No. of companies)				
	Total (36)	Specialty (13)	Basic (16)	Diversified (5)	Engineering (2)
Overseas (non-U.S.) operations	3.7	3.9	3.4	4.0	4.0
Domestic (U.S.) operations	3.3	3.5	3.1	3.4	4.0
Positive economic impact on business	3.1	3.1	3.0	3.2	4.0
Ability to compete	3.7	3.8	3.4	4.0	4.5
Enhancing internal quality management or practices	4.0	4.1	3.9	3.6	4.5
Improved quality of products or services	3.5	3.5	3.5	2.[illegible]	4.5
Simplifying or improving operating procedures or training	3.6	3.8	3.6	3.0	4.0
Relationships/interactions with customers	3.3	3.2	3.4	3.2	4.0
Relationship with suppliers	3.0	3.0	2.9	3.0	3.5
Reduced need for audits by customers and/or suppliers	3.2	3.5	2.9	3.6	3.0

Diversified manufacturers see ISO 9000 of lesser importance in the areas of internal improvements. And engineering companies ranked all areas as very important or higher, except for relationships with suppliers and in customer or supplier audits.

Companies were asked to rank the importance of ISO 9000 in 10 different areas, the results of which are shown in the table above. A ranking of five signifies crucial, four very important, three important, two mildly important, and one not at all important.

mentum has been strong ever since. With 30 member countries and eight observers, TC 207 has divided itself into six subcommittees and one working group in the areas of EMS, environmental auditing, environmental labeling, environmental performance evaluation, life-cycle analysis, terms and definitions, and environmental aspects in product standards. The full committee will meet the week of May 9 in Australia.

Like ISO 9000, the new standards are expected to be guidance documents for setting up EMS rather than prescriptive standards. "The mission of TC 207 is standardization in the field of environmental management systems and the operative words are 'management systems,'" says John E. Master, staff executive with CMA and a member of TC 207. "The standardization addresses the best known ways of managing environmental objectives and does not deal with the setting of [those] objectives."

Although not an area for direct involvement, environmental performance is a concern of TC 207, explains Master, who also is executive adviser for environmental health and safety at Arco Chemical. "But the closest TC 207 has come to addressing that is to recognize the concepts of continuous improvement and of sustainable development, and you will find those phrases in many of the developing documents." To require organizations to meet prescribed performance levels could be harmful to relationships between developing and developed countries. "We cannot use international standards to support or create trade barriers," he says.

Industry involvement

Master and Stevens are two of several U.S. chemical company representatives participating in TC 207. Master is chairman of the U.S. Technical Advisory Group (TAG) to the Environmental Performance Evaluation (EPE) Subcommittee and Stevens serves as a convener of one of its working groups. "CMA concluded very early that it didn't want TC 207 and EMS [standards development] to go the same way [as ISO 9000 had]," says Master. Assuming that the development of ISO 9000 standards would be primarily a European activity, "CMA essentially ignored the process," he explains. "But of course [it] didn't take very long to find out that [CMA's assumption] was not true."

Initially believing it would just monitor TC 207 in preparation for the outcome, Master says, "CMA very quickly recognized that there was an opportunity to influence the development of standards and really participate in the process." An ad hoc CMA committee headed by Master monitors TC 207, reviews each subcommittee's activities and progress, looks into issues that are important from a chemical industry perspective, and assesses how solid and well accepted the U.S. position is in the international arena.

CMA's committee has helped establish a chemical industry position, says Master, "but even more important, it has helped solidify positions and helped to strengthen the ability of the U.S. to advocate its positions and really achieve some pretty good results." The chemical industry is just one

of many U.S. industry groups represented on TC 207 through an ANSI TAG. "I don't want it to appear like the chemical industry is trying to grab all the glory," says Master, "but none of [the other industries] have the same kind of proactive organization and leadership that the chemical industry has."

Chemical industry representatives to TC 207 believe that chemical industry positions have been very consistent with those of the rest of U.S. industry. However, both Master and Stevens, as well as others, express concern that most of the participation has been from industry and not from other interest groups. "It means that, in the end, we may not have the degree of buy-in from other interests that we ought to have relative to the value of a voluntary standard," warns Master.

The Environmental Protection Agency and the Department of Commerce have been active, says Stevens, and work is being conducted with the National Wildlife Federation toward the inclusion of environmental interests. Liaison organizations to TC 207 also include the International Chamber of Commerce, the International Institute for Sustainable Development, the United Nations Environment Program, and the World Wide Fund for Nature. Another goal of TC 207 is to gain better representation worldwide, including that from developing or newly industrialized nations, as well as consumers and small- and medium-sized businesses.

Environmental management standards could affect international trade and environmental law, and act as tools to support voluntary private-sector initiatives such as Responsible Care, the Global Environmental Management Initiative, the CERES Principles, and the International Chamber of Commerce's Charter for Sustainable Development. In the view of one major U.S. petrochemical company, an effective international protocol would accomplish the following:

- Be simple, understandable by the public, and compatible with existing management systems.
- Focus on management systems, not on efforts to set performance or impose prescriptive operating guidelines.
- Be flexible and adaptable to a variety of operations and local operating, customer, and community needs.
- Enable local industry, community, and government interests to balance economic and environmental considerations that are based on sound science.
- Provide management the freedom to run the business at a level consistent with the company's accountability, including output requirements established by local government.

Environmental management

Despite the concerns, TC 207's subcommittees have moved ahead at a pace generally viewed as unusually fast for ISO. "At the rate that things are moving, I would expect there will be an ISO EMS standard [from the EMS Subcommittee] that will emerge by the end of 1995," says Joel B. Charm, director of occupational health and product safety at AlliedSignal and chairman of the U.S. TAG to the EMS Subcommittee. At a recent meeting in Toronto, significant progress was made in the development of working drafts of specification and general guidance documents.

The specification standards eventually may be used by an organization to comply with the EMAS or for third-party or self-certification of an organization's EMS. These standards, Charm explains, will contain core requirements that all parties agree are necessary for an EMS. "They tend to be issues that companies already should be addressing, or have in place, and have documented procedures that they are meeting requirements," he says.

For example, among the requirements are that an organization have a published environmental policy and overall environmental management principles, documented procedures, annual objectives and targets for performance, measurement systems in place, and a means for reporting on how the overall EMS is working. Charm points out that although there is agreement that companies should be reporting, there is not yet agreement on what would be needed in such a report.

Guidelines being developed, while looking at the specification standards, also will consider emerging issues. These guidelines are for issues that everyone generally agrees should be addressed, explains Charm, but for which there isn't yet an agreed upon process on how to address them. They include how an organization can go about setting up an EMS, how to get management involved, what kind of continuous improvement should exist, and what issues should be considered in external reporting.

"The specification [standards] represent compliance," Charm points out; "the guidelines are beyond compliance." At a future date—most likely when the EMS standards are revised—issues for which there is now little agreement will be considered. Despite facing regional, national, and legal questions in trying to reach a consensus on the environmental management standards, TC 207 has made much progress in a short time.

"The U.S. has been one of the major negotiators at the table," says Charm. "I guess it might be characterized as the U.S. on one hand versus the Europeans, led by the U.K., on the other. We have tended to gather a lot of support, particularly among the Asian countries and some of the European countries." Having worked very hard to prioritize its positions and build consensus within the U.S. delegation,

DNV auditor performs an ISO audit with a client.

British Environmental Standard: A model for ISO?

The British Standard Institution's (BSI) standard BS 7750 for setting up environmental management systems (EMS) has recently been republished on the strength of a very detailed pilot program. Hundreds of companies participated in "using" an early version of the standard last year, says Reg Blake, manager of business development at the U.S arm of BSI in Tysons Corner, Va. Although many countries and companies are taking a look at the standard, says Blake, they are not yet being officially certified.

The standard, first published in March 1992, is meant to be compatible with ISO 9000 standards and contains similar features, but it can also be used as a separate standard. BS 7750 has long been assumed to be a model for many of the concepts in, while not the exact format of, evolving ISO environmental management standards. BS 7750 serves to guide a company in the formation, management, and execution of an environmental policy and system. According to CEEM Information Services, some of the required elements of an EMS, under BS 7750, include the following:

- The organization must develop a full environmental plan that specifically details the objectives and targets of the EMS and the means that will be used to achieve them.
- The organization must be in compliance with all applicable environmental legislation.
- The organization's EMS must be able to respond quickly to the ever-changing world of environmental legislation.
- The organization must compile a register of all environmental regulations and legislation that affect its business and must use it to ensure that the previous requirement is met.
- A full review of the environmental impact of the organization's operations, including site assessment, must be performed.
- The organization must assign environmental management responsibilities to employees, defining exactly who will manage the EMS.
- Personal environmental targets for individual employees have to be assigned.
- The organization must train its employees to understand the potential problems that may arise if they stray from the defined EMS.
- Proof of continuous improvement in environmental performance must be provided.
- Specific procedures must have environmental targets that must either be met over time or be reviewed and changed.
- Records regarding the achievement of objectives and targets, including the disposal of waste materials, must be kept.
- Internal audits must be conducted.
- The organization must periodically review its EMS and its compliance with the standard.

the group also built liaisons with individual members of other delegations, says Charm, "so we have support for our position at the meeting as a whole.

"All of this has helped keep our consensus together ... which is very important because ultimately what will be important for the work of TC 207 is the overall acceptability of the standard when it is finally published. The U.S. fundamentally is in support of having an environmental management standard evolve through this system. ... Otherwise we would be faced with having different standards in different regions of the world and for multinational [corporations] which operate in a number of different countries. It's much easier to have one standard."

There have been a few controversial issues, he says, one of the most controversial being that of continuous improvement and how it is applied. The debate centers on whether continuous improvement should apply to emission levels—such that a company has an obligation to continually reduce emissions—or to the overall performance of a system. The latter position, supported by the U.S., seems to be carrying through in how the standard is emerging, explains Charm.

Another issue is related to the amount of detail that should be contained in public disclosures. "Our view is that we in the U.S. probably are required to disclose far more in the environmental area than any other country in the world," says Charm, who acknowledges that Germany now has extensive disclosure requirements. "When the rest of the world comes up to that standard, we would then entertain additional disclosure requirements."

The question of whether an environmental effects registry should exist is also fairly controversial, he adds. The standard appears to be emerging with the focus away from the creation of a public registry that would list the potential effects of products and their manufacture. "What we have been able to do is [say] that there should be a requirement for the determination of the environmental aspects of activities," says Charm. "And then that information should be fed into the objectives that an organization sets for itself internally, including the question of continuous improvement."

There has been much speculation that the ISO EMS standards will look like British Standard 7750, a precedent that has been tested in the U.K. this past year. "There is a certain similarity in that the concepts are the same, but some of the detail is significantly different," says Charm. To strike a compromise between European interests for more prescriptive standards and the U.S. position that the EMS standard should be as performance based as possible, much of the kind of detail which appears in BS 7750 will be taken out and may be put in an interpretative annex or guidance document.

Other subcommittees

The Environmental Audit and Environmental Performance Evaluation (EPE) Subcommittees also are making progress, says Master, who hesitates to give specifics before the subcommittees have had a chance to present their work at the TC 207 meeting in May. The Subcommittee on Environmental Aspects of Product Standards may soon present a working document, but he says the group has "backed off" on one for approval to allow more time to deal with various issues and develop a consensus.

Results are probably "several years down the road" from environmental labeling and life-cycle assessment. "These subcommittees are moving along, but they have a lot of de-

velopment work to do," he says. "There is just not the database and technology in place at the present time to really support [labeling and life-cycle assessment], and standardization is going to take a lot more work."

The EPE Subcommittee has developed a framework document to present at the Australia meeting, having tried to reach compromises on many issues between what Master calls "very strong differences of opinion [on the part of] various participating countries."

Master says much of the debate has focused on the definitions of environmental performance and EPE. "One thing that the EPE group has recognized is that environmental management can't take place in a vacuum," he explains. "It can't take top priority in every situation to the exclusion of the other requirements of an organization's total management system, which has to include the interests of the government, customers, suppliers, communities, employees, stockholders, and all the other stakeholders."

Because there are so many different views of whether an organization is performing well, adds Stevens, "guidance to assist companies in describing and evaluating their performance is one area generally recognized by stakeholders to be of great value." The current thought of the EPE Subcommittee, he says, is that there are three major areas for evaluation and consideration: An organization ought to look at how well its management systems are operating, it ought to look at how well its operational systems are working, and it should also look at the linkages between those operational systems, processes, facilities, and the environment.

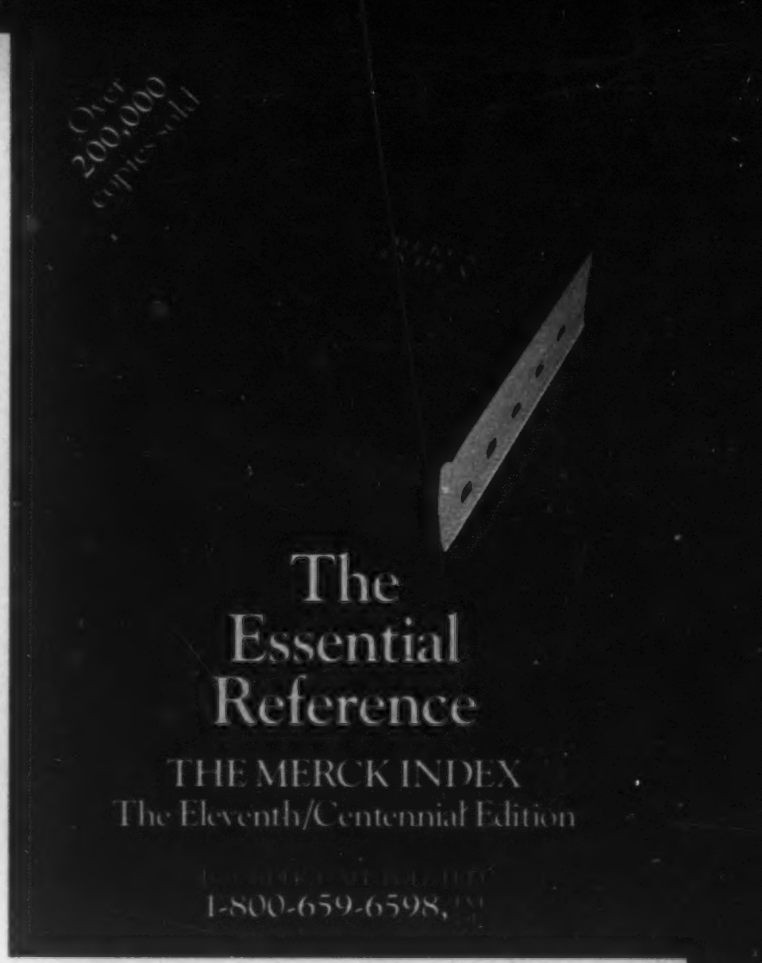
"In the end, companies can't look at 85 indicators," he says. "They are going to be looking at a handful of really critical indicators of performance and managing around those. And our process would be to give them guidelines to do that effectively and make their own choices, which will be good choices." The standards are being written to be flexible, says Stevens and others, to be used by companies for either internal or external company assessment or both.

For example, the standards would allow organizations to identify independently the specific legal or regulatory requirements they must meet and show that they are addressed within a management program. "For that reason, targets or rules absolutely will not be identified as a part of the standards-setting process," he explains. "It will simply say that the certifying company has to know the rules, it has to measure its progress, and it should be able to show evidence that it is doing that."

Implications of certification

The question remains as to what form that evidence will take and whether it will be considered credible by those outside an organization. A third-party certification process for EMS is still being developed and there are many concerns about exactly what it will require. Most of these concerns center on how much proprietary information will be made available to auditors and to what extent information about a company's environmental management is made public.

People involved in standards development suggest that third-party registration, in analogy to ISO 9000, will certify that an organization has set up an EMS. "It will be a certification that the system is in place and that it is functioning, but not the details of how it's functioning," says Charm.



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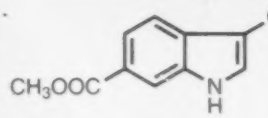
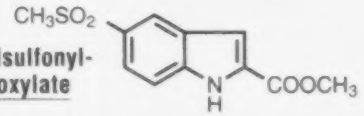


Methyl 3-Formylindole-6-carboxylate



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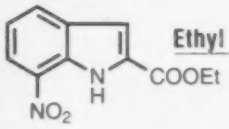

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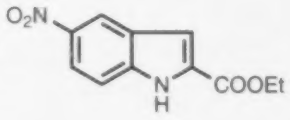

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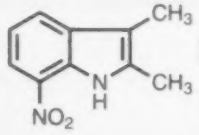
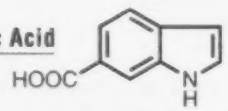
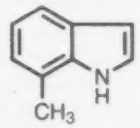


2,3-Dimethyl-7-nitroindole

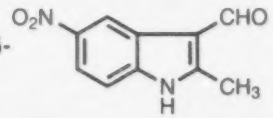
Indole-6-carboxylic Acid

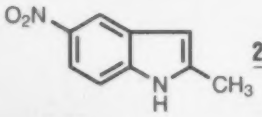




7-Methylindole

3-Formyl-2-methyl-5-nitroindole





2-Methyl-5-nitroindole

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"There will be [other] requirements in the standard for environmental audits, for performance reviews, and for an overall management review with followup improvements to be identified. So if an organization is being certified that its system is in place, then by definition it is also being certified that it has the internal systems."

There is a distinction between third-party registration for EMS and the standards work being developed by the Environmental Audit Subcommittee. This subcommittee is working to develop standards for use by organizations to internally audit their EMS to see if proper procedures are in place, that the system is adequate, and that it is being implemented. Emerging in Europe is another audit scheme, the Eco-Audit, which requires an organization to have an EMS and to make public an annual, independently verified self-assessment.

A clear distinction should be made between audit and third-party verification, says Master, because audit is a "red-flag word" in the chemical industry. Most companies look at auditing as an internal tool for the value of internal management. "The chemical industry still has a concern about release of audit findings to the public in any form," he says, "and that is a position I doubt will ever change because to [do otherwise] destroys the value of an internal audit system if your results have to be communicated. . . . It is very critical to preserve the confidentiality and the proprietary nature of that knowledge."

Public disclosure raises concerns about regulatory actions, litigation, and liability issues. "There are valid concerns within the chemical industry about 'opening the door and leaving it unlocked,'" says Stevens. "But I think there is a recognition that third parties have a real role—they do add credibility and they bring objectivity to one's own assessment—and you already see activities beginning to take place in the setting of Responsible Care to try to determine the most constructive way for third parties to be involved.

"Public disclosure will be part of this process. It's impossible to deal with the question of environmental management and environmental performance without dealing with the question of communication or reporting. You'd have to be blind not to see the very many initiatives that are around us today trying to provide guidance in this area. And one of the fundamental reasons for getting involved in ISO is to bring some uniformity and harmony to the state of the art."

Many of the companies surveyed by C&EN supported the idea of EMS standards, especially if third-party registration would reduce the number of audits by governments or regulatory agencies. Although the EMS standards are being designed to harmonize the concepts and the approach used worldwide in EMS, they will retain a degree of flexibility to allow organizations to respond to local, regional, and national laws and regulations. So, while they will level the playing field internationally in many respects, the nonprescriptive ISO standards are not anticipated to preempt local sovereignty.

However, people close to the emerging standards suggest that through environmental management standards, organizations may eventually move toward comparable levels of performance. "I believe that by improving the management of your environmental system or any other system, you are going to improve the performance," says Master. "What's going to happen over a period of time is that, by

bringing in concepts of continuous improvement and sustainable development, everybody will be driven through their management systems to better performance."

Industry reaction to EMS

The reaction to emerging environmental standards from companies surveyed by C&EN was very mixed. Although more than three quarters gave some support to the idea, the support did not extend to all of the potential elements. Others gave qualified support, depending on exactly how the EMS standards might be implemented. Reasons for support included a desire for consistent international interpretations, easier compliance with or acceptance by national regulatory bodies, increased efficiency in operating overseas, and improved environmental management worldwide.

A spokesman for one major chemical producer indicated support for environmental management standards as long as such standards are "appropriate, timely, meaningful, and nonbureaucratic." Like many other chemical company representatives, he adds that companies already audit their environmental, health, and safety management programs worldwide and "generally require higher than local standards." At the same time, support for new standards often stems from a desire to level the playing field among different local standards.

Many indicated that no environmental standards or third-party registrations were needed because of existing voluntary initiatives such as Responsible Care and regulatory reporting programs such as EPA's Toxics Release Inventory. At the same time, others welcomed third-party audits because of their involvement in these programs. Of the companies which supported environmental management standards, about half were in favor of third-party registration, generally believing it to be inevitable and, they hope, a means for companies to gain public confidence.

A spokeswoman for a global chemical company says that as a member of CMA, "the company adheres to the principles of Responsible Care which has embedded in it management principles for safety, health, and the environment. Since the company's ultimate responsibility is to society at large, it is verification to society that it is concerned about." Like many others in the industry who anticipate that third-party verification in the environmental and other arenas is an eventuality, she still questions whether this "will satisfy all interested parties."

However, a spokesman for Exxon Chemical says the company does not consider "turnkey third-party evaluations ... heavily supported by some, mostly consulting firms, who have a vested interest in the outcome" to be a sound approach. "There is no single set of environmental measures that is appropriate for differing types of businesses and facilities," says the spokesman. "The complexity is an order of magnitude more difficult than financial performance. ... Furthermore, assessment requires a combination of skills and knowledge that presently reside only within industry."

Another area in which there is little agreement is whether new standards should be separate from the ISO 9000 series. Whereas several companies believe that there would be value in having "ISO 9000-like" principles applied to environmental matters, others leveled the same, and other, criticisms as those raised for ISO 9000 standards. But by and large, in light of numerous voluntary and mandatory initi-

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atives that exist for all facets of company operations, the reaction of chemical companies was that EMS standards would be workable only if they could be combined with existing programs and auditing procedures.

CMA has focused on integrating such programs, says Master, and also is trying to respond to public demands and develop a verification process for company self-assessments under Responsible Care. One possible route is to couple the goals set through Responsible Care with ISO 9000 and EMS standards, using one third-party registration to cover all three. An important industry issue is reducing the number or audits, he adds, because plant managers are spending more time responding to audit requests—for both voluntary and regulatory programs—than concentrating on managing facilities.

Separate audits may not be needed, say registrars such as Dror at DNV and Reg Blake, manager of business development at BSI, because of the anticipated similarities in structure and documentation between EMS and ISO 9000 standards. What may be required instead is some additional assessment activity and effort on the part of the auditing team to evaluate a management system that has been expanded to cover more aspects of a company's operations. But they emphasize that auditors will need training, as they have for different industry sectors, and possibly certification to deal with environmental standards.

DuPont's plant in Wurtland, Ky., has received ISO certification.

However, there are reservations among registrars about environmental auditing. Currently, Blake says he knows of no registrars yet accredited for EMS because the accreditation bodies are considering the risks of any liabilities after certifying a company's environmental system. "It could be that only certain accreditation bodies and registrars may offer this service. It's a commercial decision that they'll make based on a risk assessment about whether to get involved in a particular market."

Based on his experience with the BS 7750 standard, Blake says that prior compliance with ISO 9000 is a "good vehicle for integrating a BS 7750 approach into the organization." In a drive to be more efficient and simplify work procedures, many companies have already started integrating programs covering different aspects of operations, with some even looking at BS 7750. And CMA has been developing guidelines showing the interrelationships between initiatives such as Responsible Care, ISO 9000, and the Occupational Safety & Health Administration's Process Safety Management.

Among the most common approaches mentioned by companies is to consolidate environmental, health, and safety requirements into quality management systems. And, although the broader total quality management systems encompass these efforts, the procedures and practices of ISO 9000 frequently are used to form the foundation for documentation, auditing, or training. Still, companies must be careful to track the elements of each separate program to demonstrate and ensure compliance.

But the question of integration, at least between the ISO 9000 and EMS standards, may be moot within a few years. "In one of the later revisions of ISO 9000, I anticipate there will be either a direct incorporation or a direct reference to what will now be the ISO 14000 series," says Charm, "such that if you want to be ISO 9000 registered in the future, I believe that you will also have to have the environmental management system in place." Thus, if the chemical industry continues its commitment to the ISO 9000 standards, it may very soon find itself without a choice. □

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